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| 10/072,681      | 02/08/2002  | Louis E. Burton      | GENENT.037C3        | 2508             |

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| EXAMINER |
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MOHAMED, ABDEL A

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| ART UNIT | PAPER NUMBER |
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1653

DATE MAILED: 08/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/072,681

Applicant(s)

BURTON ET AL.

Examiner

Abdel A. Mohamed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS**

1. The amendment and remarks filed 5/27/03 are acknowledged, entered and considered. In view of Applicant's request claim 1 has been amended and claims 2-20 have been added. Thus, claims 1-20 are now pending in the application. The objections to the abstract and title of the invention and the rejection under 35 U.S.C. § 101 double patenting for claim 1 over U.S. Patent No. 6,423,831 are withdrawn in view of Applicant's amendment and remarks filed 5/27/03. Also, the rejections under the judicially created doctrine of obviousness-type double patenting for claim 1 over U.S. Patent Nos. 6,423,831; 6,184,360; and 6,005,081 are withdrawn and modified as follows:

It is noted that Applicant has amended claim 1 and have added new claims 2-20. Thus, the following rejections are necessitated by Applicant's amendment to the claims.

### **HEADINGS FOR NONSTATUTORY DOUBLE PATENTING**

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### **DOUBLE PATENTING-NONSTATUTORY WITH PATENTS**

3. Claims 1-20 are rejected under the under the judicially created doctrine of double patenting over claims 1-22 of U.S. Patent No. 6,423,831.

The subject matter claimed in the instant application is set forth in the '831 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention as amended and the patent claim a process to isolate a neurotrophin from a mixture containing other proteins and variants of that neurotrophin and compositions thereof. The only difference between the '831 patent claims and the claims of the instant application is the scope of the claims in which the instantly claimed invention is broadly directed to neurotrophin from a mixture containing other proteins and variants of that neurotrophin compositions thereof while the '831 patent claims is specifically directed to a process to isolate a neurotrophin homolog from a mixture

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containing other proteins and variants of that neurotrophin homolog, recombinant neurotrophin and a composition thereof having various percent homolog to the sequence disclosed. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims and the disclosure of the isolation process with various purifying techniques, resins and the amino acid sequences with percent homolog thereof. The invention of the instantly claimed invention appears to be broader in scope than that of the '831 patent which is specific because the patent claims and/or encompasses the isolation of specific neurotrophin homolog using the various resins recited therewith and the disclosure of amino acid sequences with percent homolog while the instantly claimed invention claims broadly neurotrophin in general (i.e., any kind of neurotrophin) from a mixture containing other proteins and variants of that neurotrophin without claiming the amino acid sequences with percent homolog and the various purifying techniques and recited therewith. However, since both inventions claim process of isolating neurotrophins and compositions thereof; it is an obvious variation to use or adapt either the broader scope or the specific because both procedures use the same techniques for purification of neurotrophins as well as selecting the appropriate resins and percent homolog of amino acids thereof. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other. Thus, absent of showing in the claim(s), it is apparent that the isolation and/or purifying neurotrophins

and compositions thereof of current claims are an obvious variation of the patented claims.

4. Claims 1-20 are rejected under the under the judicially created doctrine of double patenting over claims 1-23 of U.S. Patent No. 6,184,360.

The subject matter claimed in the instant application is set forth in the '360 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim a process to isolate a neurotrophin from a mixture containing other proteins and variants and compositions thereof. The only difference between the '360 patent claims and the claims of the instant application is the scope of the claims in which the instantly claimed invention is broadly directed to a neurotrophin (i.e., any kind of neurotrophin) from a mixture containing other proteins and variants of that neurotrophin and composition thereof while the '360 patent claims is limited specifically to a process to isolate a neurotrophin from mixture containing variants of said neurotrophin that can include a misfolded variant, an incorrectly proteolytically processed variant, and a glycosylated variant and composition thereof. Both inventions are basically the same since they are made by the same procedure for the same purpose. Further, the instantly claimed invention in claims 2, 6 and 11 use the same resins recited in claims 2, 17 and 20 of '360 patent. Nevertheless, the only difference between the two inventions is the scope of the claims and the disclosure of the isolation process with various pHs, buffers, solvents and salt concentrations thereof. The invention of the instantly claimed invention appears to be broader in scope than

that of the 360' patent which is specific because the instant application claims and/or encompasses the isolation of any kind of neurotrophins using the various resins recited therewith with various techniques of purifications while the '360 patent claims specific neurotrophin from a mixture containing other proteins and variants of that neurotrophin with specific pHs, buffers, solvents and salt concentrations thereof. However, since both inventions are claiming process of isolating neurotrophins and compositions thereof; it is an obvious variation to use or adapt either the broader scope or the specific because both procedures use the same techniques for purification of neurotrophins as well as selecting the appropriate resins, pHs, buffers, solvents and salt concentrations thereof. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other. Thus, absent of showing in the claim(s), it is apparent that the isolation and/or purifying neurotrophins and compositions thereof of current claims are an obvious variation of the patented claims.

5. Claim 1-20 are rejected under the under the judicially created doctrine of double patenting over claims 1-25 of U.S. Patent No. 6,005,081.

The subject matter claimed in the instant application is set forth in the '081 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim a process to isolate a neurotrophin from a mixture containing other proteins and variants and compositions thereof. Both

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inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims. The invention of U.S. Patent No. 6,005,081 appears to be specific in scope than that of the instantly claimed invention of Serial No. 10/072,681 which is broader because the instant invention claims and/or encompasses the isolation of any kind of neurotrophin from a mixture containing other proteins and variants of that neurotrophin which may including recombinant while the '081 patent claims only recombinant human neurotrophins using the various resins, pHs, buffers and salt concentrations recited therewith and the instantly claimed invention claims only neurotrophin (i.e., any kind of neurotrophin) from a mixture containing other proteins and variants of that neurotrophin compositions thereof without claiming the various pHs, buffers, solvents and salt concentrations thereof. However, since both inventions are claiming process of isolating neurotrophins and compositions thereof; it is an obvious variation to use or adapt either the broader scope or the specific because both procedures use the same techniques for purification of neurotrophins as well as selecting the appropriate neurotrophins, resins, pHs, buffers, solvents and salt concentrations thereof. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other. Thus, absent of showing in the claim(s), it is apparent that the isolation and/or purifying neurotrophins and compositions thereof of current claims are an obvious variation of the patented claims.



6. **ACTION IS FINAL, NECESSITATED BY AMENDMENT**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

**CONCLUSION AND FUTURE CORRESPONDENCE**

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax

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phone number for the organization where this application or proceeding is assigned is  
(703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is (703) 308-  
0196.

*AM* Mohamed/AAM

August 18, 2003



CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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